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U-003-306 .25

DISCUSSIONS RELATED TO RESOLUTION OF RISK RELATED COMMENTS ON OPERABLE UNIT ONE DOCUMENTS

07/27/94

DOE-2138-94
DOE-FN EPA
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COMMENTS

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Department of Energy
Fernald Environmental Management Project
P. O. Box 398705
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(513) 648-3155

JUL 27 1994
DOE-2138-94

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Mr. James A. Saric, Remedial Project Director
U.S. Environmental Protection Agency
Region V-5HRE-8J
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

Mr. Thomas Schneider, Project Manager
Ohio Environmental Protection Agency
Southwest District Office
401 East Fifth Street
Dayton, Ohio 45402-29113

U-003-305.25

Dear Mr. Saric and Mr. Schneider:

DISCUSSIONS RELATED TO RESOLUTION OF RISK RELATED COMMENTS ON OPERABLE UNIT ONE DOCUMENTS

A meeting was held, between the United States Environmental Protection Agency (U.S. EPA) and United States Department of Energy (U.S. DOE), on July 7, 1994 in Chicago and a follow up conference call was made on July 20, 1994 to resolve outstanding risk related issues on the Remedial Investigation and Feasibility Study (RI/FS) reports. The meeting on July 7, 1994 was instrumental in identifying a clear path for resolution of several key risk issues related to Tentatively Identified Compounds (TICs), discussion of the bases for the selection of parameter values for the central tendency farmer receptor, and the contribution to the overall risk from the dermal pathway for beryllium.

It is the understanding of U.S. DOE that satisfactory resolution of these issues has been achieved. The purpose of this letter is to provide the U.S. DOE's interpretation of the outcome of both the aforementioned meeting and conference call. Enclosed are notes and summary interpretations relating to both the meeting and the conference call. These notes are only a means to demonstrate that the discussions took place and that these are the interpretations on behalf of the U.S. DOE and its contractor; Fernald Environmental Restoratation Management Corporation (FERMCO). Any discrepancies noted on behalf of the U.S. EPA need not be identified in any forum other than through commenting on the RI or FS documents. Agreement on the part of U.S. EPA with the resolution of the meetings and the conference call would be documented through the review and approval cycle for the RI and FS documents.

One key point should be noted as it pertains to the U.S. DOE letter transmitting draft beryllium Preliminary Remediation Goal (PRG) calculations.

risk from beryllium was to amend the methodology such that the dermal absorption factor was reduced from 1.0 percent to 0.1 percent. After U.S. EPA review of the calculations and the bases for the slope factors provided in Integrated Risk Information System (IRIS) the revised change to the calculational methodology is to base the calculated dermal slope factor on the oral slope factor using a gastrointestinal absorption factor (GI_{abs}) of 100 percent instead of the previously recommended value of 1.0 percent. In light of this modification U.S. DOE is rescinding the proposal to assume that the dermal pathway is at least as toxic as the oral and thereby only perform a comparative risk calculation. The revised method (using a GI_{abs} factor of 100 percent will provide the appropriate balance between the contribution to risk from the oral and dermal pathways as reflected in the various studies.

If you have any questions concerning the above please contact Randy C. Janke at (513) 648-3123.

Sincerely,

for Jack R. Craig
Fernald Remediation Action
Project Manager

FN:RC Janke

Enclosures: As Stated

cc w/enc:

G. Jablonowski, USEPA-V, ATI8J
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J. Kwasnieski, OEPA-Dayton
M. Proffitt, OEPA-Dayton
R. Owen, ODOH
L. August, Geotrans
F. Bell, ATSDR
J. Michaels, PRC
AR Coordinator, FERMCO

cc w/o enc:

J. J. Fiore, EM-40, TREV
K. A. Chaney, EM-423, QO
D. C. Freeman, EM-423, QO
D. R. Kozlowski, EM-423, QO
J. P. Hamric, DOE-OH
J. W. Reising, DOE-FN
G. E. Mitchell, OEPA-Dayton
P. F. Clay, FERMCO
R. T. Fellman, FERMCO
R. D. George, FERMCO
T. D. Hagen, FERMCO
S. M. Houser, FERMCO
J. W. Thiesing, FERMCO
M. K. Yates, FERMCO

HIGHLIGHTS OF DOE-EPA OU1 RI MEETING
July 7, 1994

Summary

The meeting was held to discuss comments received from the U.S.EPA (received by DOE June 27, 1994) on the Draft Final OU1 Remedial Investigation Report and Baseline Assessment (RI) and to highlight the U.S.DOE responses to risk assessment comments (mailed June 30, 1994) on the OU1 Feasibility Study (FS). Attendees included:

Jim Saric, EPA
Pat Van Leeuwen, EPA
Jean Michaels, PRC
Dave Lojek, DOE-FN
Randy Janke, DOE-FN
Scott Lloyd, PRC
R.D. George, FERMCO
Terry Hagen, FERMCO
Kirk Gribben, FERMCO
Sue Wolinsky, FERMCO

This document merely presents the U.S.DOE interpretation of the various discussions held throughout the meeting. This document does not represent a formal description or transcript of the meeting. The U.S.EPA expects 100% resolution of all issues raised during the meeting. It is U.S.DOE's interpretation that after adequate time for a complete U.S.EPA review of the resultant change pages to the FS (July 15, 1994) and the RI change pages and comment response document (July 27, 1994), that U.S.EPA would issue a final approval of both documents unless objections are noted in the responses or actions.

The U.S.DOE's interpretation is that the meeting resulted in agreement on all issues with only three exceptions, which are identified below:

RI-Specific Issues to be Resolved

The following three RI issues will be resolved according to the following strategy and schedule:

1. **Downgradient 4000 Series Wells.**
   ACTION: The discussion and clarification of this issue will be transmitted via fax to Jean Michaels of PRC (312-938-0118) by July 15, 1994. The document was faxed on July 15, 1994 and the action was successfully resolved on July 19, 1994.

2. **Documentation of CT/RME Farmer assumptions:**
   ACTION: Provide a clear explanation of the parameters and their values in the text. Additionally explain the bases for the number of hours the farmer is assumed to spend in the field in both the CT and RME scenarios as well as for individual exposure pathways. State that if the average farmer deviates from the hours identified in the assumptions that the risk will be affected accordingly. Describe the development of the RME CT parameters to an RME scenario.

3. **Discussion and Clarification of TICs:**
   ACTION: "Soften" hard statements or conclusions with words like, "In most cases" in lieu of "In all cases." TICs represent an area of great uncertainty and, as such, must be written to reflect this uncertainty in a qualitative discussion. R.D. to fax TIC revisions to Pat on July 15, Pat to review on July 18, followed by a conference call or visit to EPA by July 20. The text that results will have Pat's approval and be used in the Final RI.

FS-Specific Issues to be Resolved

Terry Hagen responded to the 6 issues that Pat Van Leeuwen identified in her FS comments. The following issues require action and will be resolved in change pages submitted to EPA on Friday, July 15, 1995:

1. **Confusing PRG terminology.**
   ACTION: Review FS Sections 2, 5, and D for language that may still be confusing; rewrite to describe PRG modification process. (See Global Issue #2, below.)

2. **Infrequent detects.**
   ACTION: Change page to explain modification of PRGs to PRLs, perhaps replacing references to "infrequent detects" with NCP language. Include further explanation of how detections in a medium (i.e., pit waste vs. surface soil) impacted decisions to develop PRLs.

3. **Adding background levels to risk (prompted by beryllium issue).**
   ACTION: Review FS Sections 2 and D to ensure the text supports Pat's stated position (see Global Issue #3, below). Say PRLs are developed based on risk, including risk from background levels. Add text that identifies the other 5 NCP factors in modifying PRGs. When background is adopted for a specific chemical, say so in text.

Global Issues Affecting All CRUs

1. **Use of one significant figure** in risk tables is considered by U.S.EPA to be unacceptable. U.S.EPA further added that use of rounding, as exhibited in OU1 RI, is confusing and reflects a misapplication of EPA direction on significant figures given to OU4. All subsequent FEMP CERCLA documents must report two significant figures. The rationale rests on RAGs, which states that one significant figure is allowed for non complicated sites; based on discussion today, EPA concluded that two significant figures is appropriate for the FEMP site, which is considered a complicated site. OU1 can use one significant figure as a result of a discussion between DOE and EPA today. Only OU1 is authorized to add a generic footnote to tables explaining use of significant figures (that the total number in the final column may be higher or lower due to rounding), and add a reference to Attachment E for specific values.

2. **PRG terminology** is confusing (PRG, modified PRGs, PRLs, FRLs): Clearly define each term used. Avoid calling the PRG modifying process "modified PRGs".

3. **Role of background in calculating total risk.** Pat's position:
   - Cannot subtract background from total risk (except for rad), per RAGs; we disagreed but will follow her guidance.
   - Treat this as a methodology issue. Consider the issue: Is the detection limit the risk limit?
   - In response to our suggestion to treat beryllium as a "special case", she said special cases "won't be the way of the future". The issue is that special cases at FEMP may not be special cases elsewhere.
   - Pat agreed to Randy Janke's suggestion that language be added to the OU1 FS that states there are special cases where risk numbers increase. However, OU5 must work with Pat to develop an acceptable strategy for OU5. Consider the issue: OU5 could revise levels

up (not down, as currently stated) if new information (i.e., amended risk assessment methodologies) become available.

- In response to DOE's disagreement with the current methodology (i.e., 1% for dermal absorption), Pat encouraged DOE to contact IRIS and ECAO directly about DOE's disagreement and proposed position, so a new, perhaps more realistic level, could be considered and EPA peer reviewed.

4. **Beryllium (Background Issue - Related Global Issue #3)**
Issue is the role of dermal absorption in determining total risk, as determined by EPA methodology. The issue was raised in the OU1-FS but has site-wide implications.
   - The following statement was agreed upon during the meeting: "This meeting recommends that the calculation for dermal absorption default to .1% because the (assumptions inherent in the) 1% has shown to be unrealistic."
   - Pat recommended recalculating the PRG for beryllium in the OU1 FS, then showing the revised calculations to her so she can determine whether the risk from dermal exposure is less or greater than the risk from oral exposure. The immediate OU1 action will be to either revise the FS per Pat's recommendation after review of these calculations or to add a footnote to the tables that reflect this calculation. This issue must be decided for other OUs.
   - Pat will consult IRIS, ECAO and other sources for ingestion versus injection absorption studies to see if any other guidance or practice is available.

HIGHLIGHTS OF DOE-EPA OU1 RI CONFERENCE CALL
July 20, 1994

Summary

The conference call was held to resolve the three outstanding issues that resulted from the July 7, 1994 DOE-EPA meeting. Participants included Pat Van Leeuwen of U.S.EPA, Randy Janke of U.S.DOE, and Kirk Gribben, Terry Hagen, R.D. George, and Sue Wolinsky, all of FERMCO.

The three outstanding issues, and their resolution, are as follows:

1. TICs - All text was reviewed and with the exception of several minor editorial revisions was considered to meet the expectations of U.S.EPA.

2. CT-RME - All text was reviewed. There were minor editorial changes made to maintain consistency or to add clarity. The text describing the CT and RME farmer was considered to be satisfactorily resolved.

3. Beryllium - The issue on beryllium was resolved by U.S.EPA after careful consideration of the IRIS data base. The information in IRIS pointed toward an absorption factor of 100% for the development of the oral slope factor. Given this, the dermal slope factor would be increased by a factor of 100 over what the U.S.DOE had previously used. Having made this correction the change proposed by U.S.DOE to treat the dermal as toxic as the oral was negated and the modification of the dermal absorption factor from 1.0% to 0.1% as recommended by U.S.EPA was also negated. For the dermal pathway the absorption factor of 1.0% will be used and the slope factor will be determined on the basis of 100% gastrointestinal absorption.

HIGHLIGHTS OF DOE-EPA OU1 RI MEETING
July 7, 1994

Summary

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July 20, 1994

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